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Chemical Policy Summit Series**

**TSCA at 2: An Update on
Implementation and Hot Topics**

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Program

Opening -- **Lynn L. Bergeson**
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Agency Update -- **Nancy B. Beck, Ph.D., DABT®**
Deputy Assistant Administrator
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Key Section 5 Concerns -- **Misty L. Bogle**
Global Product Stewardship Manager
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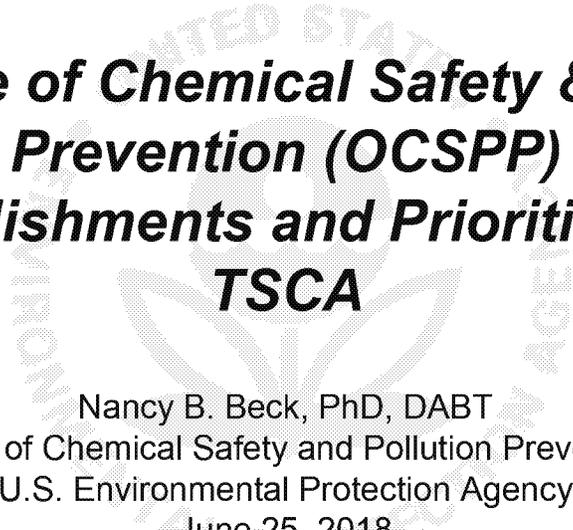
Key Section 5 Concerns -- **Michael Gould**
EH&S Committee Chairman
RadTech North America

Questions

Close



Nancy B. Beck, Ph.D., DABT®
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***EPA Office of Chemical Safety & Pollution
Prevention (OCSPP)
Accomplishments and Priorities under
TSCA***

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June 25, 2018
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Toxic Substances Control Act (TSCA) Year 2 Accomplishments

- Addressing Persistent, Bioaccumulative, and Toxic (PBT) Chemicals
- Dust-Lead Hazard Standards
- Final Mercury Reporting Rule
- Transparency and Confidential Business Information (CBI)
 - Unique Identifier
 - Generic Name Guidance
 - Expanded Access to CBI Guidance
- Alternative Strategy to Reduce Animal Testing





TSCA Year 2 Accomplishments

- New Chemicals Points to Consider
- Ten Problem Formulations
- Asbestos Significant New Use Rule (SNUR)
- Systematic Review Approach
- Proposed Fees Rule



Near-Term Priorities

- Methylene Chloride Final Rule
- Establishing a Fee Program
- Updating TSCA Chemical Substance Inventory
 - CBI Review Plan Rule
- Completing First Ten Chemicals Risk Evaluations
- Selecting the Next 40 Chemicals for Prioritization
- Addressing PBTs
- Refining New Chemicals Review



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Conditions of Use (COU)

- **Section 3 Definition:** "... the circumstances, as determined by [EPA], under which a chemical is intended, known, or reasonably foreseen to be manufactured, processed..."
- The Office of Pollution Prevention and Toxics (OPPT) considered COU in the past, including foreseeable COU, and would impose restrictions (e.g., use limitations, water release limitations) to protect against those foreseen COU

Key Concerns

- If the U.S. Environmental Protection Agency (EPA) identifies a COU in which hazard is not low for health and for ecotoxicity (“low/low” cases), EPA is proposing regulation in nearly all cases
 - Basis: “somebody might” exceed the level of concern
 - Any conceivable vs. reasonably foreseeable

Key Concerns

- If EPA determines it is required to regulate under Section 5(f) or Section 5(e), it must do so “to the extent necessary” to protect against unreasonable risk
 - What is “the extent necessary”?
- Example for consideration:
 - An employer requires workers to wear gloves and gloves are provided to all workers
 - If EPA believes that a worker may choose not to wear the required gloves, is that a foreseeable COU and reasonable basis for a SNUR? Does adding a TSCA regulation in addition to the existing Occupational Safety and Health Administration (OSHA) regulation meet the “extent necessary” provision?

Key Concerns

- Notable outcomes
 - EPA requiring workplace protection duplicative to OSHA requirements
 - Very difficult to “test out” of restrictions -- absent testing to demonstrate low hazard, EPA imposes regulation

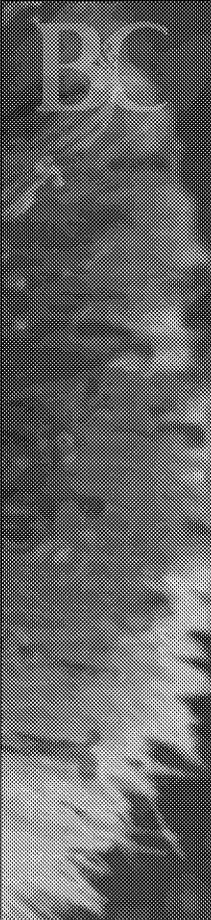
Case Study

BACKGROUND

- Stereoisomer -- non-specific analog already on TSCA Inventory
- Ester -- no releases to water, worker protections included
- Low Volume Exemption (LVE) granted -- no unreasonable risk
- Premanufacture Notification (PMN) application in June 2017
- Added aquatic test data
- Same controls in place
- PMN conditions – “not likely to present unreasonable risk”
- Concern about changes to COU -> non-5(e) SNUR

Questions for EPA

- Will we see additional guidance on the Agency's interpretation of "reasonably foreseen" circumstances in new chemical review?
- Can industry expect to be regulated in every case, unless our substance is completely non-hazardous?
- When will the backlog of non-5(e) SNURs be resolved?
- Feedback on issues of concern related to COU
- Could/should EPA revisit the option to consider relative risk?
 - Because EPA no longer considers relative risk in new chemical review, less hazardous new chemicals are more highly regulated than more hazardous existing chemicals



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Business Concerns with SNURs

- Consent order or non-order SNUR trigger
 - Section 12(b) export notification if substance present at >1 percent
 - Supply chain communication to all recipients
 - Recordkeeping requirements apply to all levels of supply chain
 - Lower reporting thresholds for Chemical Data Reporting (CDR)
- Some companies prohibit purchasing a substance with a SNUR due to a perception of enhanced risk

Current Forecast on SNURS

- Many more SNURs in our future
 - Recent analysis shows:
 - About 5 percent of initial determinations are not likely
 - 11.5 percent of final determinations are not likely
 - Is this trend reversible?
- Necessity of SNURs
 - Role of workplace standards
 - Is EPA coordinating with OSHA?

Case Study

BACKGROUND

- Pre-amended TSCA, PMN filed for substance regulated under LVE
 - Substance is low molecular weight polymer of a discreet chemical substance with known toxicity concerns
- PMN initially dropped, but pulled back into re-evaluation after amended TSCA passed

CURRENT STATUS

- Conclusion of re-evaluation under amended TSCA included certain restrictions
 - Including concentration limitation for imported products
 - Concentration limitation makes it impossible for manufacturer to import raw material
- Re-evaluation also focuses on toxicity of parent compounds versus final product

Questions for EPA

- Does EPA evaluation take into account the fact that by making the discreet substance into a polymer, the substance has less exposure potential?
 - Less accessible at the cellular level
 - More secure in final cured articles
- Does EPA have recommendations for maintaining import production volumes in circumstances in which product is not restricted in Europe?

Related SNUR Issues

- Significant delays, especially in SNUR publication
 - Order SNURs – no reason to delay; required by statute, restrictions established in consent order
 - Non-order SNURs – authority has been questioned
- Section 5(e) SNURs must be prompt
- Fish or cut bait on non-order SNURs
- Creative solutions when hazards can be addressed by limiting how substance is manufactured
 - Proposal to create new Inventory flag for chemicals with workplace exposure concerns
- Example for consideration: The EPA conservative model predicts exposure a level order of magnitude below a chemical's concentration of concern (COC)
 - Is it foreseeable that COC could be exceeded?
 - Is this a reasonable basis for a SNUR?

Questions



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Thank You

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